



MICHAEL P. WALLS
VICE PRESIDENT
REGULATORY & TECHNICAL AFFAIRS

February 5, 2019

Scott M. Sherlock, Attorney Advisor
Environmental Assistance Division
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
By email to sherlock.scott@epa.gov

Re: Comments of the American Chemistry Council on FOIA Request No. EPA-HQ-2019-001853

Dear Scott:

I am writing on behalf of the American Chemistry Council (ACC) to comment on the Freedom of Information Act (FOIA) request of Earthjustice and others for the complete, unredacted copies of 24 studies on Pigment Violet 29 submitted to EPA voluntarily.

The pending FOIA request raises important issues for the future implementation of section 6 of TSCA. If EPA rejects the confidentiality claims here and releases the complete, unredacted copies of the studies of interest, it will send a clear message to foreign owners of relevant data who may consider voluntarily submitting to EPA studies they have generated. The message would be that foreign companies (particularly European companies who have considerable information as a result of the REACH regulation) who are not subject to TSCA cannot—or should not—rely on EPA to maintain the confidentiality of their voluntarily-submitted and commercially valuable studies. It should be clear that this result would have a detrimental impact on EPA's ability to obtain confidential studies cited in REACH or other dossiers generated in foreign jurisdictions.

Under section 26(h) of TSCA, EPA must implement section 6 “consistent with the best **available** science.” Under section 26(k), EPA must take into consideration under section 6 hazard and exposure information “that is reasonably **available** to the Administrator.” EPA takes the position that robust summaries of studies are insufficient for the Agency's assessment needs under section 6—it needs full studies. This does not mean that the full studies need to be disclosed to the public.

If EPA cannot keep voluntarily-submitted and commercially valuable studies confidential, the foreign owners of those studies are not very likely to make them available to EPA on a voluntary



basis. Further, EPA's work under section 6 would be undermined by its inability to obtain the full studies that it requests, as it has in this case, to support the assessment. The net result would be that relevant information is simply not made available to the Agency.

We strongly believe that EPA can be transparent about the data and information it relies upon to make its decisions without disclosing confidential and commercially valuable information.

ACC understands that the study owners do not make any confidentiality claims for 16 of the studies requested. For the other 8 studies, those companies claim certain personal and business information as confidential, particularly some data contained in the full copies of the studies submitted to EPA.

The company that submitted the studies to EPA is a Dutch company. The studies of interest are mostly summarized in a dossier for Pigment Violet 29 submitted to European Chemical Authority (ECHA) under the European Registration, Evaluation, and Authorization of Chemicals (REACH) regulation. EPA could not require any of those companies to submit the studies. Thus, TSCA, including section 14(b)(2), does not apply.¹

Although TSCA does not apply, exemption 4 of FOIA does apply to the information that the study owners claim as confidential. EPA should review the request in light of decades of court decisions interpreting exemption 4. Of particular importance are the cases that address voluntary submissions of commercially valuable information.

ACC encourages EPA to deny the FOIA request for complete copies of the studies for which the study owners have asserted confidentiality claims and provided substantiation for those claims.

Please contact me or my colleague Christina Franz, Senior Director, Regulatory & Technical Affairs, if you have questions or comments. I can be reached at (202) 249 6400 or mike_walls@americanchemistry.com; Christina is available at (202) 249-6406 and christina_franz@americanchemistry.com.

Sincerely,



Michael P. Walls
Vice President
Regulatory and Technical Affairs

cc: Erik Baptist

¹ Even if TSCA 14(b)(2) did apply, that provision does not mandate the disclosure of health and safety studies in their entirety. See, June 6, 2018, Comments of the American Chemistry Council on CBI Claims for Underlying Data for Health and Safety Studies under TSCA.